

Prior to use they shall be examined, and as necessary, washed, rinsed, and sanitized and shall be handled in a sanitary manner.

(d) Filling, capping, closing, sealing, and packaging of containers shall be done in a sanitary manner so as to preclude contamination of the bottled drinking water.

### Subpart C—Equipment

#### § 129.40 Equipment and procedures.

(a) *Suitability.* (1) All plant equipment and utensils shall be suitable for their intended use. This includes all collection and storage tanks, piping, fittings, connections, bottle washers, fillers, cappers, and other equipment which may be used to store, handle, process, package, or transport product water.

(2) All product water contact surfaces shall be constructed of nontoxic and nonabsorbant material which can be adequately cleaned and sanitized and is in compliance with section 409 of the act.

(b) *Design.* Storage tanks shall be of the type that can be closed to exclude all foreign matter and shall be adequately vented.

### Subpart D [Reserved]

### Subpart E—Production and Process Controls

#### § 129.80 Processes and controls.

(a) *Treatment of product water.* All treatment of product water by distillation, ion-exchanging, filtration, ultraviolet treatment, reverse osmosis, carbonation, mineral addition, or any other process shall be done in a manner so as to be effective in accomplishing its intended purpose and in accordance with section 409 of the Federal Food, Drug, and Cosmetic Act. All such processes shall be performed in and by equipment and with substances which will not adulterate the bottled product. A record of the type and date of physical inspections of such equipment, conditions found, and the performance and effectiveness of such equipment shall be maintained by the plant. Product water samples shall be taken after processing and prior to bottling by the

plant and analyzed as often as is necessary to assure uniformity and effectiveness of the processes performed by the plant. The methods of analysis shall be those approved by the government agency or agencies having jurisdiction.

(b) *Containers.* (1) Multiservice primary containers shall be adequately cleaned, sanitized, and inspected just prior to being filled, capped, and sealed. Containers found to be unsanitary or defective by the inspection shall be reprocessed or discarded. All multiservice primary containers shall be washed, rinsed, and sanitized by mechanical washers or by any other method giving adequate sanitary results. Mechanical washers shall be inspected as often as is necessary to assure adequate performance. Records of physical maintenance, inspections and conditions found, and performance of the mechanical washer shall be maintained by the plant.

(2) Multiservice shipping cases shall be maintained in such condition as to assure they will not contaminate the primary container or the product water. Adequate dry or wet cleaning procedures shall be performed as often as necessary to maintain the cases in satisfactory condition.

(c) *Cleaning and sanitizing solutions.* Cleaning and sanitizing solutions utilized by the plant shall be sampled and tested by the plant as often as is necessary to assure adequate performance in the cleaning and sanitizing operations. Records of these tests shall be maintained by the plant.

(d) *Sanitizing operations.* Sanitizing operations, including those performed by chemical means or by any other means such as circulation of live steam or hot water, shall be adequate to effect sanitization of the intended product water-contact surfaces and any other critical area. The plant should maintain a record of the intensity of the sanitizing agent and the time duration that the agent was in contact with the surface being sanitized. The following times and intensities shall be considered a minimum:

(1) Steam in enclosed system: At least 170 °F for at least 15 minutes or at least 200 °F for at least 5 minutes.